

Surgery versus stent for malignant gastro-duodenal obstruction.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20885

Source

NTR

Brief title

SUSTENT study

Health condition

randomized, multicenter study

Sponsors and support

Primary sponsor: ZonMW

Intervention

Outcome measures

Primary outcome

Total area under the survival curve, adjusted for the ability to eat at least soft solids (GOOSS score of 2 or more).

Secondary outcome

1. Procedure-related (within 7 days) and long term (later than 7 days) minor and major

complications;

2. Reinterventions or recurrent obstructions;

3. Survival, calculated from day of randomization;

4. Health related quality of life, including the perceived burden of the procedure, burden of reintervention and generic and disease specific HRQoL;

5. Cost and cost-effectiveness.

Study description

Background summary

Objective:

To compare a surgical procedure(gastrojejunostomy, GJJ) with endoscopical stent placement in patients with malignant gastric outlet obstruction (GOO).

Design:

Randomized, multicenter study.

Study population:

Patients with inoperable distal stomach, periampullary or duodenal carcinoma.

Intervention:

GJJ (laparoscopic or open) or duodenal stent placement.

Outcome measures:

1) Medical effects (ability to eat, complications, reinterventions, survival), 2) Quality of life, and 3) Costs and Cost-effectiveness.

Power:

The sample size calculation is based on total time that patients are not able to eat at least a soft diet after both procedures. For this, a log transformation was performed. Assuming that stent patients are approximately 7 days earlier able to eat a soft diet after treatment, but develop more recurrent obstruction, 2x70 patients are needed for a 84% power at the 5% level (t-test). We will include 2x74 patients to compensate 5% lost to follow-up.

Analysis:

Chi-square test, t-test, Kaplan-Meier method/log rank test and non-parametric analyses with bootstrap techniques.

Economic evaluation:

GJJ and stent placement will be compared in a cost-effectiveness analysis from a societal perspective, including hospital care, health care after discharge, and informal care.

Study objective

To compare a surgical procedure (gastrojejunostomy, GJJ) with endoscopical stent placement in patients with malignant gastric outlet obstruction (GOO)

Intervention

1. Duodenal stent placement;

2 - Surgery versus stent for malignant gastro-duodenal obstruction. 3-05-2025

2. Gastrojejunostomy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Obstructive cancer (more than 25% of the circumference as seen by endoscopy) extending from the distal duodenum;
2. Gastric outlet obstruction scoring system (GOOSS) score of 0 (no oral intake) or 1 (liquids only);
3. Incurable or metastatic disease;
4. Informed consent.

Exclusion criteria

1. Evidence of other strictures in the gastrointestinal (GI) tract;
2. Previous gastric, periampullary or duodenal surgery;
3. Previous (palliative) treatment for the same condition;
4. WHO performance score of 4 (patient is 100% of time in bed);
5. Unable to fill out quality of life questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2006
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion	
Date:	13-12-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

NTR-new

NTR-old

Other

ISRCTN

ID

NL489

NTR531

: 945-06-503

ISRCTN6702358

Study results

Summary results

N/A